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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/623,307 | 03/21/2001 | Naoto Oku | 50026/024001 | 2668 |

7590
Paul T Clark
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Boston, MA 02110

05/21/2002

EXAMINER

EPPS, JANET L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1635

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,307

Applicant(s)

OKU ET AL.

Examiner

Janet L. Epps

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 26-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have amended claim 26 to recite wherein said polyalkylenimine or said salt comprises...(b) seven or more nitrogen atoms, and (c) a base skeleton that does not comprise a carbonyl group.” As support for this amendment Applicants reference page 10, lines 7-10 and 19-23 which states that a molecular weight of 300 Da for polyethylenimine corresponds to approximately seven ethylenimine units, and thus seven nitrogen atoms, in a molecule. Furthermore, Applicants argue that since 300 Da is a lower limit, seven nitrogen atoms is a lower limit. However, contrary to Applicant’s assertions, the specification as filed, page 10, lines 7-10, does not disclose “300 Da” as a molecular weight. The term “Da” or Dalton does not accompany the term “300” as recited on page 10 of the specification. It is unclear what unit of measurement Applicants are referring to on page 10 of the specification. In the examples,

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however, Applicants describe the weight of the synthesized polyethylenimine compounds in terms of grams and moles. Moreover, it is unclear what calculations Applicants used to determine wherein a molecular weight of 300 Da, corresponds to a polyethylenimine of seven nitrogen atoms. Applicants have not accounted for the contribution of other molecules in the polyethylenimine structure.

Additionally, Applicants have amended the instant claims to recite wherein the base skeleton of the polyalkylenimine does not comprise a carbonyl group. Again, Applicant's specification does not provide adequate support for this limitation. Although the terminology "a saturated or unsaturated acyloxycarbonyl group" has been removed from the claims, formulas I, II, and III, on pages 11-12 of the specification as filed clearly encompasses polyalkylenimines comprising a carbonyl group.

Applicant's amendment to claim 26 constitutes new matter, since the specification as fails to provide proper antecedent basis for the claimed subject matter, particularly wherein the polyalkylenimines of claim 26 comprise "... (b) seven or more nitrogen atoms, and (c) a base skeleton that does not comprise a carbonyl group." See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

Applicant is required to cancel the new matter in the reply to this Office Action.

4. Claims 26-29 remain rejected under 35 USC 102(b) as being anticipated by Khmel'nitsky et al. for the reasons of record set forth in the Official Action mailed 8-29-01.

Applicant's arguments filed 3-08-2002 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that claim 26 (and its

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dependent claims), as amended, require a water-soluble composition containing a polyalkylenimine including a base skeleton and two or more hydrophobic groups. According to Applicants, the compounds of Khmelnitsky et al. are "slightly soluble in water" but highly soluble in organic solvents. However, since the instant claims merely recites "water-soluble" and does not clearly set forth the metes and bounds of what Applicants deem "water-soluble," to the extent that the compounds of Khmelnitsky et al. are to some extent "water-soluble," albeit slightly, the compounds of this reference are deemed to anticipate the instant claims.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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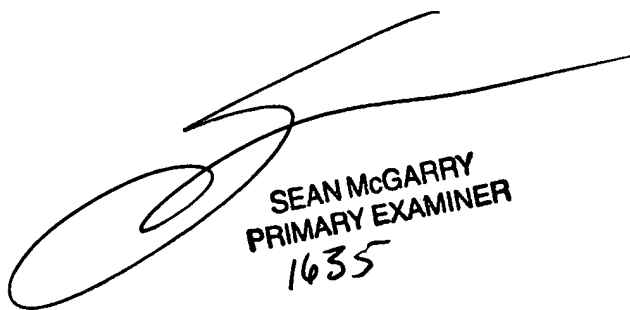
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps
Examiner
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jle
May 17, 2002



SEAN MCGARRY
PRIMARY EXAMINER
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